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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,548	02/20/2001	Hana Koutnikova	ST00005	5202

29693 7590 09/27/2002

WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/27/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,548	KOUTNIKOVA ET AL.	
	Examiner	Art Unit	
	Robert Hayes	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *32-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 32-45, 53, and 59, (each in part) drawn to a polypeptide and pharmaceutical compositions comprising the same, classified in class 514, subclass 2, for example.

II. Claims 32-35, 46-50, and 57-58, (each in part) drawn to gene therapy compositions wherein the nucleic acid comprises SEQ ID NO: 1, classified in class 514, subclass 44, for example.

III. Claims 32-35, 51-52, and 54, (each in part) drawn to an antibody directed against a peptide and pharmaceutical compositions comprising the same, classified in class 530, subclass 387.1, for example.

IV. Claims 32-35 and 55-56, (each in part) drawn to a compound which possesses an active motif capable of mimicking a peptide having the amino acid sequence of SEQ ID NO: 2, classification dependent upon compound structure.

V. Claim 60 (in part), drawn to a method of screening a compound comprising selecting a compound capable of binding to a peptide having the sequence of SEQ ID NO: 2, classification dependent upon structure of compound.

VI. Claim 60 (in part), drawn to a method of screening a compound comprising selecting a compound capable of binding to a peptide having the sequence of SEQ ID NO: 4, classification dependent upon structure of compound.

VII. Claims 61 and 62, drawn to a method for producing a polypeptide comprising culturing a cell containing a nucleic acid under conditions for expressing said nucleic acid, and recovering the peptide produced, classified in class 435, subclass 69.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions V, VI, and VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention V requires search and consideration of SEQ ID NO: 2, which is not required by any of the other Inventions. Invention VI requires search and consideration of SEQ ID NO: 4, which is not required by any of the other Inventions. Invention VII requires search and consideration of producing a peptide, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, II, III, and IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The polypeptide of Invention I is independent and distinct from the product of Invention IV because it is not required to make or use the polypeptide of Invention I. The nucleic

acid and vectors of Invention II can be used other than to make the protein of Invention I, such as a probe in nucleic acid hybridization assays or therapeutic methods (e.g. gene therapy). Additionally, the polypeptide of Invention I can be obtained using the antibody of Invention III, it can be obtained through materially different methods such as chemical synthesis or isolation from natural sources. The nucleic acid and vectors of Invention II are independent and distinct from the products of Inventions I, III, and IV because none are required to make or use the nucleic acid and vectors of Invention II. The antibodies of Invention III are independent and distinct from the products of Inventions II and IV because neither is required to make or use the antibody of Invention III. Although the antibody of Invention III can be used to obtain the polypeptide of Invention I it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The compound of Invention IV is independent and distinct from the products of Inventions I, II, and III because none are required to make or use the compound of Invention IV.

5. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The polypeptide of Invention I can be used in therapeutic methods.

6. Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The nucleic acid and vector of Invention II can be used in therapeutic methods such as gene therapy.

7. Inventions VII and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Invention I can be made by materially different processes such as chemical synthesis or isolation from natural sources.

8. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and VI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed method of Invention VI does not recite the use or production of the polypeptides of Invention I.

9. Inventions II and each of V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of V and VI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of

Inventions V and VI do not recite the use or production of the nucleic acid and vectors of Invention II.

10. Inventions III and each of V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of V, VI, and VII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions V, VI, and VII do not recite the use or production of the antibody of Invention III.

11. Inventions IV and each of V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of V, VI, and VII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions V, VI, and VII do not recite the use or production of the compound of Invention IV.

12. FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 32-62, each in part, as the inventions pertain to SEQ ID NO: 2.

B. Claims 32-62, each in part, as the inventions pertain to SEQ ID NO: 13.

C. Claims 32-62, each in part, as the inventions pertain to SEQ ID NO: 15.

D. Claims 32-62, each in part, as the inventions pertain to SEQ ID NO: 43.

E. Claims 32-62, each in part, as the inventions pertain to SEQ ID NO: 45.

13. The inventions are distinct, each from the other because of the following reasons:

14. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Inventions A, B, C, D, and E are directed to sequences that are distinct both physically and functionally, and are not required one for the other. Invention A requires search and consideration of SEQ ID NO: 2, which is not required by any of the other Inventions. Invention B requires search and consideration of SEQ ID NO: 13, which is not required by any of the other Inventions. Invention C requires search and consideration of SEQ ID NO: 15, which is not required by any of the other Inventions. Invention D requires search and consideration of SEQ ID NO: 43, which is not required by any of the other Inventions. Invention E requires search and consideration of SEQ ID NO: 45, which is not required by any of the other Inventions. Each sequence requires a separate search of the literature and sequence databases. A search and examination of an Invention as it pertains to all sequences would therefore present the examiner with an undue search burden.

15. Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect one group from I-VII. In order to be fully responsive, Applicant must elect one group from I-VII and one group from A-E if Applicant chooses any one of Inventions I, III, or VII.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Hayes whose telephone number is 703-305-3132. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
September 26, 2002